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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,409

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Samuel M. Shaolian

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Medtronic

Attn: Noreen C. Johnson, IP Legal Department

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EXAMINER

BECCIA, CHRISTOPHER J

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/606,409	Applicant(s) SHAOLIAN ET AL.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, and 4-19 have been considered but are moot in view of the new ground(s) of rejection. Please direct attention to rejection below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 1, and 4-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,746,451 to *Middleton et al.* in view of U.S. Patent No. 6,863,672 to *Reiley et al.* in further view of U.S. Patent No. 5,542,434 to *Imran et al.* and in further view of U.S. Patent No. 5,178,625 to *Groshong*.

As to **Claim 1**, *Middleton* discloses an enucleation device (100) comprising:
a cutting cap (130) comprising a plurality of elastically deformable blades (120) sized and shaped for cutting a portion of a spinal segment (Col. 6, Lines 4-29), the deformable blades deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another and an insertion configuration where the deformable blades extend generally parallel to one another, wherein the orthogonally-expanded cutting configuration is a neutral position for the deformable blades and the insertion configuration is a deformed position for the

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deformable blades such that when the deformable blades are not deformed the deformable blades return to the orthogonally-expanded cutting configuration (Col. 6, lines 4-29, describe the undeformed, neutral, outward blade in Fig. 3A, and deformed insertion configuration in Fig. 3B); wherein the deformable blades are positioned radially about a central opening extending through the cutting cap to allow the cutting cap to be placed over a guidewire (Blades 130 positioned radially when 120 is coaxial with 14, and tube 14 can be placed over a guidewire);

a hollow shaft (14) fixedly connected to the cutting cap, the shaft connected to the cutting cap (Fig. 3A-3C), the hollow flexible shaft including an axial lumen (110) extending along the length of the hollow flexible shaft (14) and in communication with the central opening of the cutting cap such that the, hollow flexible shaft is configured to be placed over the guidewire (Figs. 3A-3C);

a motor adapter (12) positioned adjacent to the proximal portion of the hollow flexible shaft (Fig. 2A), the motor adapter configured to connect the enucleation device to a motor drive for rotating the flexible shaft to cause rotation of the cutting cap (Col. 5, Lines 29-43);

where the plurality of elastically deformable blades can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed (Col. 6, Lines 4-29); and

where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material (Col. 9, Lines 29-55);

As to **Claims 4-6, 11, 14, 18, and 19**, *Middleton* discloses a method of cutting material in a space, comprising: providing device (As disclosed in Claim 1 above) having a proximal end, a distal end comprising a cutting cap sized and shaped for cutting a portion of a spinal segment (Col. 5, Lines 44-67 – Col. 6, Lines 1-29), the cupping cap comprising a plurality of deformable blades formed of shape memory alloy (Col. 6, Lines 30-47); wherein the deformable blades are deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another and an insertion configuration where the deformable blades extend generally parallel to one another (Col. 6, lines 4-29, describe the undeformed, neutral, outward blade in Fig. 3A, and deformed insertion configuration in Fig. 3B), wherein the shape memory alloy of the deformable blades is processed such that the orthogonally-expanded cutting configuration is a neutral position for the deformable blades and the insertion configuration is a deformed position for the deformable blades such that when the deformable blades are not deformed the deformable blades return to the orthogonally-expanded cutting configuration (Col. 6, Lines 30-64); a motor adapter (12) positioned adjacent to the proximal end, the motor adapter configured to connect the enucleation device to a motor drive for rotating the flexible shaft to cause rotation of the cutting cap (Col. 5, Lines 29-43);

As to **Claims 7 and 12**, *Middleton* discloses a method comprising advancing and retracting the device in the space to cut additional material (Col. 9, Lines 28-55).

As to **Claims 9, 10 and 15-17**, *Middleton* discloses wherein the material cut is intervertebral disk and vertebral endplate material; and advancing the device through a transpedicular access passage in a vertebra (Fig. 13A and Col. 10, lines 40-54).

As to **Claims 1, and 4-19**, *Middleton* teaches the claimed invention except for wherein there are multiple deformable blades; wherein the passage is curved; wherein the shaft is flexible; wherein advancing the cutting device through the passage comprises advancing the cutting device over a guide wire; a hypotube positioned around at least a proximal portion of the hollow flexible shaft and fixedly connected to a user graspable handle of the enucleation device; and a shrink tube positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap, the shrink tube having a reduced outer diameter relative to the hypotube such that the shrink tube provides a bearing surface between the hollow flexible shaft and the hypotube.

Reiley discloses a transpedicular approach for creating a cavity in a vertebral body (Col. 1, Lines 42-50, Col. 9, Lines 45-50); wherein there are multiple deformable blades (Fig. 9- Fig. 11 and Col. 6, Lines 6-46); wherein the passage is curved (Fig. 11); and wherein the shaft is flexible (Col. 1, Lines 51-52) in order to provide an instrument and method capable of establishing a percutaneous path leading to bone, providing a shaft adapted to be deployed inside bone including a cavity forming structure carried by the shaft comprising a surface which directly contacts and shears cancellous bone in response to linear movement of the shaft along the axis of the cannula (Col. 1, Lines 66-67 - Col. 2, Lines 1-16) while providing a cutting surface that prevents unnecessary

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damage to the bone during insertion, yet doesn't require a deployment step (Col. 6, Lines 18-23).

Groshong teaches an enucleation device wherein advancing the cutting device through the passage comprises advancing the cutting device over a guide wire (Col. 11, Lines 15-62) in order to provide additional support and ease for introducing the enucleation device into the cavity (Col. 11, Lines 15-62).

Imran discloses an introduction device, including a hollow shaft (31); a hypotube (22) positioned around at least a proximal portion of the hollow flexible shaft and fixedly connected to a user graspable handle of the device (Figs. 5 and 7, Col. 5, Lines 1-14); and a shrink tube positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap (Col. 4, Lines 16-19), the shrink tube having a reduced outer diameter relative to the hypotube such that the shrink tube provides a bearing surface between the hollow flexible shaft and the hypotube (Fig. 4, Col. 4, Lines 16-19) in order to provide an assembly capable of housing a guide wire that can be deflected in vivo, relatively long, and easily inserted into the patient (Col. 1, Lines 17-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tool and method of *Middleton* with the blade and shaft modifications of *Reiley*, guide wire of *Groshong* and hypotube and shrink tube of *Imran* in order to provide an instrument and method capable of establishing a percutaneous path leading to bone, providing a shaft adapted to be deployed inside bone including a cavity forming structure carried by the shaft comprising a surface which directly contacts and shears cancellous bone in response to linear movement of the shaft along the axis

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of the cannula, while providing a cutting surface that prevents unnecessary damage to the bone during insertion, yet doesn't require a deployment step; to provide additional support and ease for introducing the enucleation device into the cavity; and in order to provide an assembly capable of housing a guide wire that can be deflected in vivo, relatively long, and easily inserted into the patient.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775